LZI Oral Fluid Amphetamine Controls

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Rx ONLY

Lin-Zhi International, Inc.

REF		Description	Quantity
S0046b	CONTROL -	LZI Oral Fluid Amphetamine 37.5 ng/mL Control	1 x 5 mL
S0047b	CONTROL +	LZI Oral Fluid Amphetamine 62.5 ng/mL Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Amphetamine Controls are for use as assayed quality control materials to monitor the precision of the LZI Oral Fluid Amphetamine Enzyme Immunoassay (Ref# S0040b/S0041b) on a number of automated clinical chemistry analyzers.

Description of the Controls:

The LZI Oral Fluid Amphetamine Controls are in a negative synthetic oral fluid matrix, and ready to use. The constituent is a synthetic human oral fluid matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The controls are prepared by spiking known concentrations of *d*-amphetamine into the drug-free matrix. Controls are made from NIST traceable standards.

*****Actual concentrations of these controls are within ±10% of the target value as determined by GC/MS. Values are provided only as guidelines and laboratories should determine the ranges based on their own test system and tolerance (1).

Precautions and Warning

- *The LZI Oral Fluid Amphetamine Controls are for in vitro diagnostic use only. Harmful if swallowed.*
- *The controls contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azide. When disposing such liquids always flush with a large volume of water to prevent azide build-up.*
- *The controls are prepared from a non-sterile synthetic oral fluid matrix. Always apply good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the Controls beyond their expiration dates.*

Preparation and Storage

The controls are ready-to-use. No reconstitution is required. Label the cap before removal to identify it with the original bottle. The controls should be stored refrigerated at 2-8 ^{o}C when not in use.

Stability

When stored refrigerated at 2-8 ^{o}C, the controls are stable either opened-recapped, or unopened, until the expiration date printed on the vial label. Store controls tightly capped when not in use. Any control solution dispensed into the sample cups and left on board the clinical analyzer should be discarded after use.

Procedure and Results

Both levels of controls (37.5 and 62.5 ng/mL) should be run daily to ensure proper assay performance. Additionally, run with each new calibration and after specific maintenance or troubleshooting procedures are performed. For interpretation of results, refer to the appropriate LZI Oral Fluid Amphetamine Enzyme Immunoassay (Ref# S0040b/S0041b) package insert (2).

Limitations

The Oral Fluid Amphetamine Drugs-of-Abuse Controls are for use with the LZI Oral Fluid Amphetamine Enzyme Immunoassay to detect *d*-amphetamine in human oral fluid only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Bibliography

1. Guidance for Industry and FDA Staff, Assayed and Unassayed Quality Control Material. U.S. Department of Health and Human Services. FDA, Document issued on June 7, 2007.
2. LZI Oral Fluid Amphetamine Enzyme Immunoassay (Ref# S0040b/S0041b) package insert.

Notice: Adulteration of reagents, use of instruments without appropriate capabilities, or other failure to follow instructions as set forth in this labeling can affect performance characteristics, and stated or implied label claims.

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